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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,057

Applicant(s)

BROWN, COLIN

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12,14-18,21-24,26-35 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12,14-18,21-24,26-35 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1623

DETAILED ACTION

1. The amendment filed July 10, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 3, 13, 19, 20, 25, and 37 have been canceled.
 - (B) Claims 1, 6-8, 12, 18, 23, 29-31, 39, and 40 have been amended.
 - (C) Comments regarding Office Action have been provided drawn to:
 - (a) 112, 2nd paragraph rejection, which has been withdrawn;
 - (b) 112, 1st paragraph rejection, which as been maintained for the reasons of record;
 - (c) 103(a) rejection, which has been maintained over Claims 22, 23, 24, 26-35 and 40-43.
2. Claims 1, 2, 4-12, 14-18, 21-24, 26-35, and 39-43 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. Claims 1-12, 14-18, 21, 22, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, line 4 and Claim 12, line 2; in the absence of the specific moieties intended to effectuate modification by "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein Applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties Applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed. Claims 2, 3-11, 14-18, 21, 22, and 39 are also rejected since these claims are dependent from Claim 1 and do not clarify the term "substituted".

5. Applicant's arguments with respect to Claims 1-12, 14-18, 21, 22, and 39 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1623

Claim Rejections - 35 USC § 112, 1st Paragraph

6. Claims 1-35, 37 and 39-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the incidence of adhesion of tissues in or associated with a body cavity, does not reasonably provide enablement for preventing the incidence of adhesions of tissues in or associated with a body cavity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive. Applicants argue against the rejection of the claims on the ground that the term "prevention" in the instant claims is not used in an absolute sense, but in the manner known to one of ordinary skill in the art. Applicants argue that for several decades, in the course of studying the etiology of post-surgical adhesions and their "reduction", investigators and experts on the subject have been referring to interventions and devices as being either effective or not effective in preventing post-surgical adhesions. Applicants argue that numerous scientific publications and books on the subject use terminology of "adhesion prevention", although it is recognized that indeed adhesions are reduced because not all adhesions are prevented. Applicant arguments have been carefully considered, but are not persuasive. In the above underline statement presented by Applicant in the arguments, Applicants have admitted on the record that "not all adhesions are prevented". While Applicant may act as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). No such definition for the term "prevention" which has been redefined contrary to its ordinary meaning is noted in the instant specification. The declaration under 37 C.F.R. §1.132 presented by Anthony Luciano, M.D., which further characterizes "adhesion prevention" as a commonly used description for one of ordinary skill in the art of surgical medicine,

Art Unit: 1623

also admit that "it is recognized that indeed adhesions are reduced because not all adhesions are prevented" and does not present any evidence that the instantly claimed composition would be effective in preventing the incidence of adhesion. Hence, the declaration of Anthony Luciano, M.D., does not overcome the rejection of the claims under 35 U.S.C. 112, first paragraph. Accordingly, the rejection of the Claims 1, 2, 4-12, 14-18, 21-24, 26-35, and 39-43 under 35 U.S.C. 112, first paragraph, for not providing enablement for preventing the incidence of adhesions of tissues in or with a body cavity is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

8. Claims 22 and 40-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US Patent No. 5,258,175) for the reasons already of record on page 3 of the Office Action mailed May 21, 2002.

9. Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive. Applicant amended the claims to recite "that the dextrin is not substituted with strongly acidic groups selected from the group consisting of sulphate, nitrate, and phosphate groups" which overcomes the rejection of Claims 1, 2, 4-10, 12, 13, 17 and 18 against the Davies patent. However, Claim 22 still recites the presence of dextrin sulphate in the composition. It is further noted that Applicant arguments against the Davies patent are based on how the claimed composition comprising dextrin will be used. Applicant is reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F.2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claims 22 and 40-43 under 35 U.S.C. 103(a) as being unpatentable over the Davies patent is maintained for the reasons of record.

10. Claims 1, 2, 4-12, 14-18, 21, 22, 39 and 40-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Davies (US Patent No. 5,258,175) for the reasons set forth on pages 6-8 of the Office Action mailed February 11, 2003.

Art Unit: 1623

11. Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive. The instant claims are directed to a composition comprising an aqueous formulation containing a polysaccharide dextrin. The arguments presented by the Applicant against the rejection of the claims over the Viegas et al and Davies patents are base on differences in how the instantly claimed composition is used compared to the use of the compositions set forth in the Viegas et al and Davies patent. Applicant is reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claims 1, 2, 4-12, 14-18, 21, 22, 39 and 40-43 under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al patent in view of Davies patent is maintained for the reasons of record.

12. Claims 23, 24 and 26-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Milner (US Patent No. 4,886,789) for the reasons already of record on pages 5 and 6 of the Office Action mailed May 21, 2002.

13. Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive. Applicant argues that the Viegas et al patent does not proposed a method of preventing or reducing the incidence of adhesions in a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to prevent or reduce the incidence of such adhesions, wherein the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other as recited in Claim 23. This argument is not persuasive since the Viegas et al patent discloses at column 5, lines 2-6, the injection of a composition that may be used as a medical device for the separation of organs, injured in surgical procedures or otherwise, prevent the formation of undesirable adhesions as part of the healing process, which embraces the

Art Unit: 1623

instantly claimed method of preventing or reducing the incidence of adhesions in a body cavity. See column 6, lines 10 and 11 and line 34 of the Viegas et al patent wherein the aqueous pharmaceutical vehicles used in the Viegas et al patent contains a film forming polymer and the film forming polymer may be selected as polydextrin, which is within the scope of the polysaccharide dextrin set forth in the instant claims. Applicant further argues that the combination of the Viegas et al with the Milner patent does not teach or suggest the present invention. The Milner patent, which discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture - which broadly encompassed dextrin, is cited to show that the application of such a polymer to the peritoneal cavity is well known in the art. Accordingly, the rejection of Claims 23, 24 and 26-35 under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al patent in view of the Milner patent is maintained for the reasons of record.

Summary

14. Claims 1-35, 37 and 39-43 are rejected.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1623

Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

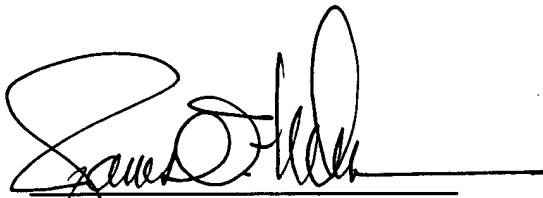
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600